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| 10/534,387 | 11/22/2005 | Timo Hillebrand | 050372 | 2884 |

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12/28/2006

EXAMINER

STAPLES, MARK

ART UNIT

PAPER NUMBER

1637

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 12/28/2006 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/534,387

Applicant(s)

HILLEBRAND ET AL.

Examiner

Mark Staples

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-56 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 35-56 is/are rejected.
- 7) ☒ Claim(s) 41 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05/06/2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 09/08/2005.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Objections

2. Claim 41 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 41 recite that the carrier materials are "solid phase materials" which is not further limiting as independent claim 35 already recites providing a "solid carrier".

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 41-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 41 recites the limitation "to isolate chaotropic reagents" in line 1. There is insufficient antecedent basis for this limitation in the claim. It is noted that the preamble of the method in claim 35 recites "isolating nucleic acids". Claim 42 is rejected as being dependent on rejected claim 41.

The term "ionically weak" in claim 43 is a relative term which renders the claim indefinite. The term "weak" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The "solutions" of this claim are thus rendered indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 35-38, 40, 43-48, 50, 51, and 53-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Seed et al. (EP 0 580 305 A2 published 1994), cited on the Information Disclosure Statement, IDS.

Independent claim 35 relates to a method for isolating nucleic acids. Technical features are a solid phase and the binding and washing solutions. Claim 35 is not restricted to solutions without alcohol or solutions with multivalent and monovalent cations.

Regarding claim 35 and 53, Seed et al. disclose a method and a test kit for isolating nucleic acids (see claims 1-23) containing multivalent and monovalent cations and a specific pH value is set (examples 1, 4-8, 11). In addition, Seed et al. describe magnesium chloride as a multivalent salt component and sodium chloride and potassium chloride as monovalent salt components (examples 1, 4-8, 11). The method of Seed et al. also isolates DNA from complex mixtures (examples 11, 9). The monovalent and the multivalent salt components are used in different molar ratios (example 5).

Further regarding claim 35, Seed et al. teach a method for isolating nucleic acids from a solution by binding to a solid phase comprising the steps of:

- a. providing a solution containing at least one nucleic acid (see Examples 1-11);
- b. combining said solution with additives containing multivalent cations and monovalent cations (see Examples 1, 4-8, 11);
- d. providing a solid carrier; e. contacting said solution with said carrier and binding said at least one nucleic acid to said carrier (see Examples 1-11);
- f. removing said nucleic acid from said carrier using a washing buffer, wherein said washing buffer has a pH between 5 and 10 and:
- i. does not comprise alcohol (see Examples 1-10).

Regarding claim 36-38, Seed et al. disclose a method where a multivalent and/or monovalent cations in said washing buffer are metallic cations; and where the monovalent KCl is 0.05 M or 50 mM, multivalent $MgCl_2$ is 10 mM, and the ratio of these is 50:10 or 5:1 which is within the ratio range of about 9:1 to about 1:9 (see Example 5).

Regarding claim 40, Seed et al. disclose a method further comprising addition of tris-HCl to the solution containing at least one nucleic acid (see Example 7).

Regarding claims 43, 47, and 51 Seed et al. disclose a method where monovalent and multivalent salt components are present in ionically weak solutions and the monovalent cation is K^+ at pH 8.5, which is in the range of 8.5-9.5 (see Example 3).

Regarding claims 44, 45, and 46, Seed et al. disclose methods consisting of water, Tris-HCl, and the divalent cation Mg^{2+} (see Examples 1-7).

Regarding claim 48, Seed et al. disclose a method the final concentration of salt components is >5 mMol (see Example 5).

Regarding claim 50, Seed et al. disclose methods where the pH value of the binding buffer is adjusted with Tris-HCl; since by using Tris-HCl the pH is adjusted as a property of Tris-HCl, and the pH is maintained by the buffering property of Tris-HCl (see Examples 1-11).

Further regarding claim 53 and 55, Seed et al. disclose a device (see claims 17 and 18), a kit, to isolate DNA from any base materials comprising:

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- a. an aqueous solution comprising monovalent and/or multivalent cations (see Example 5);
- d. a solid carrier produced centrifuge tube (see Examples 1-11 and it is noted that the tube can be of any dimensions which can be arranged in many configurations including 96 or 384 formats);
- e. washing buffer; and
- f. elution buffer (see Examples 1-11).

Regarding claim 54 and 56, Seed et al. disclose a device (see claims 17 and 18), a kit, where the solid phase is a membrane with polymer functional groups, PHS.

5. Claims 35, 49, and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by Hawkins (U.S. Patent No. 5,898,071 issued 1999).

Regarding claim 35, Hawkins teaches a method for isolating nucleic acids from a solution by binding to a solid phase comprising the steps of:

- a. providing a solution containing at least one nucleic acid (see Examples 1-7);
 - b. combining said solution with additives containing multivalent cations and monovalent cations (see Examples 1-7 for KOAc and Mg₂OAc);
 - d. providing magnetic particles, a solid carrier (see Examples 1-7);
 - e. contacting said solution with said carrier and binding said at least one nucleic acid to said carrier (see Examples 1-7);
 - f. removing said nucleic acid from said carrier using a washing buffer,
- wherein said washing buffer has a pH of 7.2 or 7.8 which is between 5 and 10 and:

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i. does not comprise alcohol (see Examples 1-7).

Regarding claim 49, Hawkins teaches a method wherein said alcohol is polyethylene glycol (see claim 2).

6. Claims 35 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (U.S. Patent No. 6,274,308 issued 2001).

Regarding claim 35 and 39, Lee et al. teach a method for isolating nucleic acids from a solution by binding to a solid phase comprising the steps of:

- a. providing a solution containing at least one nucleic acid (see Examples);
- b. combining said solution with additives containing multivalent cations and monovalent cations (see Examples 1 for KCl and $MgCl_2$);
- d. providing a membrane, a solid carrier (see Examples 1-10);
- e. contacting said solution with said carrier and binding said at least one nucleic acid to said carrier (see Examples 1-10);
- f. removing said nucleic acid from said carrier using a washing buffer, wherein said washing buffer has a pH of 8.9 which is between 5 and 10 and:

ii. comprises an alcohol, ethanol, and at least one monovalent and/or multivalent cation (see Example 1).

Conclusion

7. No claim is allowed.

8. Claims 41 and 42 are rejected for lack of antecedent basis.

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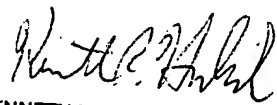
9. Claims 35-40 and 43-56 are not free of the prior art.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Staples whose telephone number is (571) 272-9053. The examiner can normally be reached on Monday through Thursday, 9:00 a.m. to 7:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark Staples
Examiner
Art Unit 1637
December 19, 2006

MS


KENNETH R. HORLICK, PH.D.
PRIMARY EXAMINER

12/20/06